

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission, filed 7/11/11, has been entered.

Amended claims 1 and 9, filed 7/11/11, are acknowledged. Claims 22-23 and 26 remain withdrawn from consideration due to being drawn to non-elected Groups. Claims 2, 3, 13, 14, 17, 20, 27-30, and 32 are withdrawn from consideration due to being drawn to non-elected species.

Claims herein under examination are 1, 4-12, 15-16, 18-19, 21, 24, 25, and 31.

### **Claim Rejections - 35 USC §102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21 (2) of such treaty in the English language.

Claims 1, 4-12, 15-16, 18-19, 21, 24, 25, and 31 are rejected under 35 U.S.C. 102(a) and (e) as being anticipated by Blumenfeld et al. (US 6,528,260 B1).

Blumenfeld et al. disclose a method for determining the probability of exhibiting a phenotypic attribute (col. 9, fourth paragraph; col. 67, third paragraph; col. 80, last two paragraphs; col. 84, first paragraph to col. 86, first paragraph), as stated in the preamble of instant claim 1 as well as the determining step of instant claim 9. Blumenfeld et al. disclose evaluating genomic markers for zygosity from a preselected set of markers wherein each preselected marker has a degree of linkage with one or more of the one or more phenotypic attributes (col. 10, fourth paragraph; col. 13, last paragraph to col. 14, first paragraph; col. 16, last paragraph to col. 17, first paragraph; col. 67, third paragraph; col. 73, second paragraph; col. 74, second paragraph; col. 79, second and third paragraphs; col. 84, second paragraph), comparing zygosity of preselected markers to a multivariate scoring matrix to obtain a matrix score that correlates patterns, whereby marker priority incorporates local genome context information in the comparison (col. 14, last paragraph; col. 31 [BLAST], 32, 33, and col. 83, second paragraph) as well as determining whether the marker score indicates enhanced, diminished, or average probability of exhibiting a phenotypic attribute (col. 84, second paragraph to col. 86, first paragraph; col. 91, second paragraph) using software on a computer (col. 87, second paragraph; col. 97, second paragraph to col. 98, last paragraph), as stated in instant claims 1, 9. Blumenfeld et al. disclose using promoter sequences (col. 10, last paragraph; col. 31, first paragraph; col. 64, fifth paragraph), as stated in instant claims 4 and 5. Blumenfeld disclose selecting markers prioritized by degree of phenotypic significance and markers that map at least

about 1000 discrete loci (col. 39, last paragraph to col. 40, first paragraph; col. 79, third paragraph; col. 89, line 47 to col. 90, first paragraph), as stated in instant claim 7. Blumenfeld et al. disclose performing analysis when some information concerning the biology of the trait is available (col. 21, second paragraph) and selecting markers from some of the Tables (i.e. 11A-B; col. 12, third paragraph; col. 17, first three paragraphs; col. 25, second paragraph) which represents scoring matrix prioritizing markers with respect to criteria of quality of supporting research, as stated in instant claims 1, 8, 9, 31. Blumenfeld et al. disclose assessing individual risk (col. 9, first paragraph), screening markers with higher probabilities (col. 65, lines 53-55; col. 87, lines 60-67), identifying genotypic characteristics of an individual that correlate with phenotypic characteristics (claim 1 col. 9, first paragraph; col. 10, fourth paragraph; col. 67, third paragraph; col. 80, last two paragraphs), displaying output to a user (col. 98, last paragraph) and accessing information on the computer (col. 97, last paragraph), as stated in instant claim 9. Blumenfeld et al. disclose genotyping individuals for a DME-related biallelic marker that is selected individually or in combination with other markers (col. 13, last paragraph), detecting an association between an allele and a phenotype (col. 14, second paragraph), reiterating experiments at least 100 times (col. 90, fourth paragraph), looking at various phenotypic trait selection criteria, such as clinical phenotype, age, family history, and severity (col. 84, second paragraph) as well as other criteria such as drug treatment responses, including drug treatments having different degrees of response or side effects (col. 84, last two paragraphs), determining probabilities of phenotypes (col. 84, second paragraph), formatting tables of information, and outputting to a user (i.e. col. 98, last paragraph; col. 103, last paragraph; Tables 10, 11A-B, 21, 22, 23), analysis regarding probability that person with a given genotype will exhibit a trait (col.

9, fourth paragraph), as stated in instant claims 9, 10, 15, 16, (and i.e. see Tables above, inherently prior to communication to individual, the identity of individual is not associated with data, as stated in instant claim 21). Blumenfeld et al. disclose studying physiological consequences at the cellular and organism level (col. 45, last paragraph to col. 46, first paragraph), various databases with information on sequence variations and how genotypes affect common diseases, drug responses, and other complex phenotypes (col. 111, first and third paragraphs), and user-specified thresholds of significance (col. 32, first paragraph) as stated in instant claims 11 and 12. Blumenfeld et al. disclose taking into account effects of subpopulations with discriminatory potential or considering close familial relationships (col. 110, second paragraph) which represents an organizational matrix that groups phenotypic characteristics related to similar physiological systems together, as stated in instant claim 18. Blumenfeld et al. disclose assessing risk to better target therapeutic strategies defining individual drug usage based on benefit/risk prognosis as well as efficacy/tolerance prognosis (col. 9, first paragraph) and scoring the results of determination of the identity of a nucleotide at a marker with respect to the test subject's risk of contracting disease, drug response, or chances of suffering side effects (col. 41, second paragraph) which represents ranking phenotypic characteristics as a function of potential impact on the individual's lifestyle, as stated in instant claim 19. Blumenfeld et al. disclose characteristics of genomic ethnicity of an individual (col. 64, last paragraph; col. 95, fifth paragraph). Blumenfeld et al. disclose diseases including disorders of male infertility (col. 27, first paragraph) and studies among affected relatives by analysis of two individuals, including sib pair analysis (col. 80, second paragraph). Blumenfeld et al. disclose population-based association studies (col. 83, last paragraph) and inclusion criteria for

selection as well as linkage studies and statistical analysis (col. 83, second to last paragraph to col. 85, last paragraph), and pharmacogenomic analysis (col. 1, second paragraph), as stated in instant claims 24 and 25.

Thus, Blumenfeld et al. anticipate the instant invention.

Applicant summarizes the instant invention. Applicant argues Blumenfeld et al. do not disclose determining marker priority or incorporating marker priority in a multivariate scoring matrix to obtain a marker score. This statement is found unpersuasive as Blumenfeld et al. disclose using BLAST and BLOSUM62 scoring matrix which compares sequences by comparing aligned sequences (col. 31, 32) which inherently represents prioritizing markers with respect to homology to another marker sequence of interest. Applicant argues that he has clarified marker priority to incorporate local genome context information. However, it is noted that Blumenfeld et al. disclose comparing two optimally aligned sequences (col. 31, second paragraph) which represents marker priority incorporating local genome context information in the comparison. The probability of a phenotype score given by Blumenfeld et al. (col. 87, last paragraph) results in a percentage value that would inherently indicate an enhanced, diminished, or average probability of exhibiting a phenotypic attribute. Applicant's arguments are deemed unpersuasive for the reasons given above.

### *Conclusion*

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform to the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The Central Fax Center number for official correspondence is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran, can be reached on (571) 272-0720.

August 22, 2011

/Carolyn Smith/  
Primary Examiner  
AU 1631